IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

CURTIS SIMPSON AND JAMES MAYO as Next of Kin and natural sons of CLAUDIA SUE HALL, deceased,	§	
Plaintiffs,	§	
v.	§	**Docket No.** 3:09-CV-429 **JURY DEMAND**
	§	Varlan/Shirley
K-V PHARMACEUTICAL COMPANY, ETHEX CORPORATION, CVS CAREMARK CORPORATION and CVS PHARMACY, INC.	§	
Defendants.	§	

COMPLAINT

PARTIES AND JURISDICTION

Come now the Plaintiffs, Curtis Simpson and James Mayo, by and through their undersigned counsel, and file this action for the wrongful death of their natural mother Claudia Sue Hall, deceased against the above-named Defendants and state as follows:

1. Plaintiff Curtis Simpson is a citizen and resident of Anderson County, Tennessee residing at 114 Aspen Lane, Oak Ridge, Tennessee 37830.

2. Plaintiff James Mayo is a citizen and resident of Knox County, Tennessee residing at 3615 Fulton Road, Corryton, Tennessee 37721.

3. Plaintiffs are the next of kin, natural sons, and only children of Claudia Sue Hall, deceased.

4. The Defendant K-V Pharmaceutical Company (hereinafter "Defendant K-V") is a Delaware corporation with its principal place of business located at 2503 Hanley Road, St Louis, Missouri 63144. Defendant K-V may be served through its registered agent CT Corporation System 120 South Central Ave., Clayton, MO 63105.

5. The Defendant Ethex Corporation (hereinafter "Defendant Ethex") is a Missouri corporation, and wholly owned subsidiary of Defendant K-V, with its principal place of business located at One Corporate Woods Drive, St. Louis, Missouri 63044. Ethex may be served through its registered agent CT Corporation System 120 South Central Ave., Clayton, MO 63105.

6. Defendant CVS Caremark Corporation (hereinafter "Defendant CVS Caremark") is a Delaware corporation with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895. Defendant CVS Caremark may be served through its registered agent CT Corporation System 155 South Main Street, Suite 301, Providence, RI 02903.

7. Defendant CVS Pharmacy, Inc., (hereinafter "Defendant CVS Pharmacy") is a Delaware corporation, and wholly owned subsidiary of Defendant CVS Caremark, with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895. Defendant CVS Pharmacy may be served through its registered agent CT Corporation System 155 South Main Street, Suite 301, Providence, RI 02903.

8. At all times herein material, Defendant K-V designed and manufactured pharmaceutical products, including generic morphine sulfate tablets, for marketing and distribution by Defendant Ethex Corporation to pharmaceutical retailers in Tennessee and throughout the United States.

9. At all times material, Defendants CVS Caremark and CVS Pharmaceutical operated retail pharmacies, known as CVS, in Tennessee and throughout the United States selling name brand and generic pharmaceuticals as well as other non-pharmaceutical consumer goods.

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 in that there exists complete diversity between the parties and Plaintiffs allege the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

11. Venue is proper pursuant to 28 U.S.C. § 1391. The Defendants have sufficient minimum contacts with Tennessee or otherwise intentionally availed themselves of the consumer markets within Tennessee through the promotion, sale, marketing and/or distribution of their products in Tennessee and to decedent Claudia Sue Hall.

FACTUAL ALLEGATIONS

12. Prior to September 28, 2008, decedent Claudia Sue Hall resided in Oliver Springs, Tennessee and obtained prescription medications from Defendant CVS Caremark and/or Defendant CVS Pharmaceuticals operating as CVS in Oliver Springs, Tennessee.

13. Also prior to September 28, 2008, decedent moved form Oliver Springs, Tennessee and established residence at 137 Lancaster Road in Anderson County, Oak Ridge, Tennessee. While residing in Oak Ridge, Tennessee the decedent also obtained prescription medications from Defendant CVS Caremark and/or Defendant CVS Pharmacy operating as CVS in Oak Ridge, Tennessee.

14. Prior to September 28, 2008, decedent received a prescription for 15 mg Morphine Sulfate ER tablets (hereinafter "morphine tablets") for use in pain management.

15. Decedent presented the prescription and had it filled at CVS Pharmacy in Oak Ridge, Tennessee. The prescription was filled with 15 mg Morphine Sulfate ER tablets manufactured by Defendant K-V and distributed by Defendant Ethex.

16. Upon information and belief, on or about September 28, 2008, decedent consumed the subject morphine tablets as prescribed.

17. On September 28, 2008, decedent was found collapsed and near death in her Oak Ridge, Tennessee residence.

18. Decedent was subsequently transported to University of Tennessee Memorial Hospital where she was pronounced dead. At that time the attending physician ordered toxicology studies to assist with determining the cause of death.

19. Although according to the attending physician and Death Certificate decedent's date of death was September 28, 2008, the cause of death remained unknown to the Plaintiffs until November 18, 2008, when the toxicology studies were complete and Darinka Mileusnic, M.D., issued a Delayed Report of Diagnosis - Death stating that decedent died from a drug overdose which included morphine intoxication.

20. Approximately three weeks after the November 18, 2008, Report of Death, Plaintiffs received word from the landlord of decedent's former Oliver Springs, Tennessee residence that he recently received a letter addressed to decedent from CVS/pharmacy concerning decedent's morphine tablet prescription.

21. The undated letter (attached hereto as Exhibit A) contained "CVS/pharmacy" letterhead and was address to decedent. It was intended to advise decedent that: 1) Ethex Corporation had advised CVS of a voluntary recall of certain 15 mg Morphine Sulfate ER tablets, 2) that decedent had received from CVS morphine tablets from the lot(s) recalled by Ethex, and 3) the recall was due to oversized tablets which contained up to twice the stated dosage of morphine.

22. The undated, CVS/pharmacy letter was not issued by decedent's pharmacist or any pharmacist but was signed by Marsh Moore, M.D., MBA, Senior Vice President, Medical Affairs, CVS Caremark.

23. Plaintiffs receipt of the CVS/pharmacy letter was the first notice Plaintiffs had that their mother had ingested defective morphine tablets sold by CVS and manufactured and distributed by Defendants K-V and Ethex, respectively.

24. Upon information and belief, on June 10, 2008, the U.S. Food and Drug Administration issued a MedWatch E-mail warning to all named Defendants stating that Ethex had distributed K-V manufactured 60 mg Morphine Sulfate tablets that were too thick and contained up to twice the stated dosage of morphine. The FDA warned that any consumers that begin or continue to take this drug are at the risk of morphine overdose which could lead to breathing problems, erratic behavior, seizures, low blood pressure, nausea, vomiting and even death. Ethex then issued a voluntary recall of the 60 mg tablets.

25. Between June 10, 2008 and September 28, 2008, the FDA and/or Ethex issued multiple, additional warnings and/or recalls for other drugs manufactured by K-V, distributed by Ethex and sold by the CVS Defendants because of poor manufacturing processes that continually caused the final drugs to contain substantially more of the active ingredient than stated on the wholesale and/or prescription labels.

26. On or about November 7, 2008, Ethex issued a voluntary recall of the subject 15 mg Morphine Sulfate ER tablets, manufactured by K-V, due to the tablets being too thick and containing up to twice the stated dosage of morphine.

27. Decedent received the defective 15 mg morphine tablets from CVS and ingested them prior to and/or on September 28, 2008.

28. At the time Defendant K-V manufactured and Defendant Ethex distributed the subject 15 mg morphine tablets, all Defendants knew or should have known that K-V's manufacturing practices had in fact failed to produce, and continued to fail to produce, morphine and other drugs in tablet or pill form which contained the proper dosage of the active ingredients.

COUNT I - Strict Liability

29. Paragraphs 4-28 above are hereby incorporated by reference.

30. This is a product liability action as defined by T.C.A. § 29-28-102 for the wrongful death of decedent Claudia Sue Hall. As such, Plaintiffs bring this action on grounds of strict liability in tort;

negligence; breach of warranty, express and implied; misrepresentation; concealment; and nondisclosure, whether negligent or innocent.

31. Defendant K-V designed, formulated, manufactured, tested, and placed the subject 15 mg morphine tablets into the stream of commerce by providing them for marketing and distribution to their wholly owned subsidiary, Defendant Ethex. At the time the subject tablets were designed, manufactured and distributed, Defendant K-V and Defendant Ethex had one or more common officers and directors.

32. At all times pertinent to this case, the morphine tablets that were prescribed to, purchased by and consumed by decedent were in the same condition as when was they left the control of Defendants K-V and Ethex.

33. Plaintiffs allege that the morphine tablets received by decedent and recalled by Ethex were in a defective or unreasonably dangerous condition at the time that they left the control of Defendant's K-V and Ethex.

34. The morphine tablets consumed by decedent were unreasonably dangerous in that they were dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them with the ordinary knowledge common of the community as to their characteristics. Moreover, the morphine tablets were unreasonably dangerous because a reasonably prudent manufacturer and/or distributor of pharmaceuticals would not have placed them on the market in their dangerous condition.

35. As such, Defendants K-V and Ethex are strictly liable to decedent and Plaintiffs for designing, formulating, compounding, manufacturing, distributing and selling the morphine tablets which, at the time they left Defendants' control, were unsafe for normal or anticipated handling and were unreasonably dangerous.

36. The defective and/or unreasonably dangerous condition of the morphine tablets proximately caused the injuries to and the death of decedent.

37. Defendants K-V and Ethex had a duty to provide decedent with morphine tablets in their intended, stated, and labeled dosage so as to prevent an overdose of morphine or adverse reaction with other drugs. Defendants K-V and Ethex breached that duty in that they provided decedent with morphine tablets containing twice or as much as twice the labeled dosage of morphine.

38. Defendant K-V was in the business of manufacturing and distributing through Ethex the morphine tablets and both Defendants represented to the decedent that the tablets she received were of a certain character (i.e., properly manufactured to a specific dose). In fact that representation was not true, and the dose was two (2) times its stated amount. Decedent could not reasonably be required to know that the Defendants' representations were untrue, and therefore she justifiably relied upon those representations, resulting in an overdose of morphine that proximately caused her death.

39. As such, Defendants K-V and Ethex are strictly liable for the misrepresentations regarding the character, quality and/or safety of the morphine tablets manufactured and sold to decedent, even if those misrepresentations were innocent and non-negligent.

40. Defendants K-V and Ethex failed to timely discover and/or disclose, or concealed, the fact that the recalled morphine tablets contained two (2) times their intended dosage, and were therefore defective or unreasonably dangerous to decedent. Such failure to disclose, and/or concealment, resulted in decedent's death as she had reasonably relied upon what she believed to be administration of the proper dosage of morphine as prescribed.

COUNT II - Negligence and Failure to Warn

41. The allegations set forth in the foregoing paragraphs are incorporated herein by reference as though set forth at length verbatim.

42. On said dates and times, Defendants K-V and Ethex were negligent in that they: (a) failed to properly design, manufacture, test, label, research, distribute and sell a medical product that was safe for its intended use; (b) failed to timely and adequately notify and warn persons of the unreasonably dangerous and defective condition of the morphine tablets; (c) failed to adequately inspect and test the morphine tablets to determine that they were safe and not defective and unreasonably dangerous; (d) failed to warn physicians, hospitals, pharmacists, and patients of the morphine tablet's defective and unreasonably dangerous condition; (e) failed to adequately warn physicians, hospitals, and patients of the potential hazards of the drug; and (f) failed to exercise due and reasonable care.

43. Decedent died as a direct and proximate result of these negligent acts and omissions.

COUNT III - Negligence *Per Se*

44. The allegations set forth in the foregoing paragraphs are incorporated herein by reference as though set forth at length verbatim.

45. At all times pertinent hereto, Defendants K-V and Ethex had an obligation not to violate the law, in the design, development, manufacture, production, formulation, compounding, testing, inspecting, processing, assembling, distribution, marketing, labeling, packaging, preparation for use, release, sale and warning of the risks and dangers of the subject morphine tablets.

46. At all times pertinent hereto, Defendants K-V and Ethex violated the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301, et seq., related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes, and regulations in the manufacture, labeling and distribution of the subject morphine tablets.

47. Decedent was a purchaser and consumer of morphine tablets within the class of persons the statutes and regulations described above are to protect, and the injuries she sustained and her subsequent death were the exact type of harm these statutes were designed to prevent.

48. The actions of Defendants K-V and Ethex constitute an adulteration and misbranding as defined by the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 331, and the regulations promulgated therefrom, and constitute a breach of duty subjecting them to civil liability for all damages arising therefrom, under theories of negligence *per se*.

49. The manufacturing, production, testing, inspection and distribution processes of Defendants K-V and Ethex are not good manufacturing processes under the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 331 and the regulations promulgated therefrom, and constitute a breach of duty subjecting said Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se*.

50. The acts and omissions set forth herein demonstrate that Defendants K-V and Ethex failed to meet the standard of behavior and action set by the applicable statutes and regulations, which were intended for the benefit of decedent, making said Defendants negligent *per se*. Decedent's death was a direct and proximate result of the acts and omissions of said Defendants.

COUNT IV - Fraud/Intentional Misrepresentation

51. The allegations set forth in the foregoing paragraphs are incorporated herein by reference as though set forth at length verbatim.

52. Defendants K-V and Ethex fraudulently, intentionally, willfully and wantonly, purposefully, knowingly, recklessly, negligently and/or in fact materially misrepresented both affirmatively and by omission that the subject recalled morphine tablets were of good quality, non-defective, safe for their intended use, merchantable, and fit for their particular purpose.

53. Defendants K-V and Ethex intended, knew, and/or should have known that decedent would be induced by the aforesaid misrepresentations to use the subject morphine tablets as prescribed.

54. In using the subject morphine tablets, decedent justifiably relied on said Defendants' representations that its morphine tablets were of good quality, non-defective, labeled accurately, not

adulterated and were safe for their intended use, merchantable, and fit for their particular purpose.

55. The recalled morphine tablets were, in fact, misbranded, adulterated, defective and/or unreasonably dangerous, as recited above.

56. As a direct and proximate result of the defective or unreasonably dangerous recalled morphine tablets as well as Defendants' affirmative misrepresentations and omissions, decedent died.

COUNT V - Negligent Misrepresentation

57. The allegations set forth in the foregoing paragraphs are incorporated herein by reference as though set forth at length verbatim.

58. Defendants K-V and Ethex, in addition to knowing misrepresentations, made negligent misrepresentations without any reasonable grounds for believing their statements to be true to the decedent.

59. Said Defendants, through their negligent misrepresentations, intended to induce justifiable reliance by decedent. Furthermore, said Defendants, through their labeling, marketing campaigns, and communications with treating physicians, were in a relationship so close to the decedent it was de facto privity.

60. Said Defendants owe a duty to the medical community, decedent, and other consumers, to conduct appropriate and adequate inspections and tests for all of their products, including the recalled morphine tablets, to use safe and good manufacturing and production practices, and to provide appropriate and adequate information and warnings, but they failed to do so.

61. Said Defendants failed to conduct appropriate or adequate inspections and tests on the recalled morphine tablets.

62. As a direct and proximate result of said Defendants' negligent misrepresentations, the decedent died.

COUNT VI - Breach of Implied Warranties

63. The allegations set forth in the foregoing paragraphs are incorporated herein by reference as though set forth at length verbatim.

64. Based on the foregoing allegations, Defendants K-V and Ethex are liable to the decedent for breach of an implied warranty of fitness and a breach of an implied warranty of merchantability pursuant to Tenn. Code. Ann. § 47-2-314 and Tenn. Code. Ann § 47-2-3 15.

COUNT VII - Negligence of CVS Defendants

65. On information and belief, Defendants CVS Caremark and CVS Pharmacy received notice of actually or potentially dangerous and defective 15 mg morphine tablets and other generic drugs sold by CVS stores and manufactured and distributed by Defendants K-V and Ethex prior to September 28, 2008.

66. Although this information may or may not have been communicated to individual CVS pharmacists, CVS corporate employees and not individual CVS stores or pharmacists (See Attached Exhibit A) undertook to send notice letters to CVS customers warning of drug recalls and potentially defective prescriptions.

67. Plaintiffs allege that the non-pharmacist, corporate employees of Defendants CVS Caremark and CVS Pharmacy are not medical professionals within the purview of the Tennessee Medical Malpractice Act, and therefore no notice is required prior to filing suit as to these Defendants for failure to timely warn CVS customers of defective drugs.

68. Although Defendants CVS Caremark and CVS Pharmacy knew of the defective nature of the subject 15 mg morphine tablets and multiple other defective drugs manufactured and distributed by Defendants K-V and Ethex, their non-pharmacist, corporate officers and employees were negligent in that they failed to timely and adequately notify both their pharmacies and customers of the unreasonably

dangerous and defective condition of the subject morphine tablets. Specifically, they failed to timely and adequately warn decedent of her defective prescription prior to September 28, 2008.

69 Such delay by Defendants CVS Caremark and CVS Pharmacy corporate employees resulted in their pharmacies distributing the misbranded 15 mg morphine tablets in violation of Tennessee Food, Drug and Cosmetic Act T.C.A. § 53-1-109.

70. Decedent died as a direct and proximate result of said Defendants' negligent acts and omissions.

COUNT VIII - Punitive Damages

71. The allegations set forth in the foregoing paragraphs are incorporated herein by reference as though set forth at length verbatim.

72. Defendant K-V's and Ethex's intentional and/or fraudulent actions described herein represent a conscious objective or desire to engage in the conduct aforementioned, and thereby foreseeably caused the resulting death to Claudia Sue Hall, which would not have occurred but for the intentional acts described herein, entitling the Plaintiffs to punitive damages pursuant to Hodges v. S.C. Toof and Co., 833 S.W.2d 896 (Tenn. 1992).

73. Defendants K-V and Ethex acted recklessly by being aware of, but consciously disregarding, the substantial and unjustifiable risk of and deliberately failing to meet their respective duties as described herein. Such recklessness disregard constitutes a gross deviation of reasonable action and/or behavior, and foreseeably led to the death of Claudia Sue Hall, which would not have incurred but for the recklessness described herein, entitling the Plaintiffs to punitive damages pursuant to Hodges v. S.C. Toof and Co., 833 S.W.2d 896 (Tenn. 1992).

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, the Plaintiffs pray as follows:

74. That the Court issue Process to the Defendants requiring a response to this Complaint within the time allowed by law;

75. That the Plaintiffs be granted a trial by jury;

76. That the Plaintiffs have judgment against the Defendants, and be awarded general and compensatory damages in the amount of Two Million Dollars ($2,000,000) for the conscious pain and suffering and wrongful death of Claudia Sue Hall including the pecuniary value of decedent's life and Plaintiffs loss of consortium with their natural mother.

77. That the Plaintiffs have judgment against the Defendants K-V and Ethex and be awarded punitive damages in an amount sufficient to both punish said Defendants and to deter similar conduct in the future, as a result of the said Defendants' intentional, fraudulent, malicious, and/or reckless conduct with regard to the design, manufacture, marketing and distribution of defective 15 mg Morphine Sulfate ER tablets, as determined in the sound discretion of the jury;

78. That the Plaintiffs be awarded costs of this litigation including discretionary costs; and

79. That the Court award such other relief, both legal and equitable, as it may deem necessary.

Respectfully submitted this 28th day of September, 2009.

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